

**Special 510(k) Summary**  
**Line Extension to the OASYS<sup>™</sup> System**

Proprietary Name:	Stryker Spine OASYS <sup>®</sup> System	<b>MAR 18 2010</b>
Common Name:	Spinal Fixation Appliances	
Proposed Regulatory Class:	Class II	
	21 CFR 888.3070 (b)(1): Pedicle Screw Spinal System, 21 CFR 888.3050: Spinal Interlaminar Fixation Orthosis	
Device Product Code:	87 MNI: Orthosis, Spinal, Pedicle Fixation 87 KWP: Appliance, Fixation, Spinal Interlaminar	
For Information contact:	Pauline Shand Regulatory Affairs Associate 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8105 Fax: (201) 760-8305 Email: Pauline.Shand@Styker.com	
Date Summary Prepared:	February 16, 2010	

**Predicate Device Identification**

Stryker Spine OASYS<sup>®</sup> System: K032394, K052317, K062853, K072568, and K080143

**Predicate Device Description**

The Stryker Spine OASYS<sup>®</sup> System is comprised of rods, polyaxial screws, bone screws, hooks, connectors, and an occiput plate. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from Titanium alloy and CP Titanium and are provided non-sterile. The Stryker Spine OASYS<sup>®</sup> System can also be linked to the Xia<sup>®</sup> System, SR90D System and Xia<sup>®</sup> 4.5 Spinal System via the rod-to-rod connectors.

**Description of Device Modification**

This Special 510(k) submission is intended to introduce a line extension to the predicate OASYS<sup>®</sup> System, which consists of the addition of a new midline occiput plate, bone screws, and a Vitallium<sup>®</sup> rod

**Intended Use:**

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the Stryker Spine OASYS<sup>®</sup> System is intended for: Degenerative Disc Disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); Spondylolisthesis; Spinal Stenosis; Fracture/Dislocation; Atlanto/axial fracture with instability; Occipitocervical dislocation; Revision of previous cervical spine surgery; and Tumors.

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Stryker Spine OASYS<sup>®</sup> System can also be linked to the Xia<sup>®</sup> System, SR90D System and Xia<sup>®</sup> 4.5 Spinal System via the rod-to-rod connectors.

**Statement of Technological Comparison:**

Testing has demonstrated that the additional midline occiput plate, bone screws and Vitallium<sup>®</sup> rod have equivalent mechanical properties to the predicate OASYS<sup>®</sup> System K032394, K072568, and K052317. Both the new components and the existing system components are intended to address the same indications for use.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Stryker Spine  
% Ms. Pauline Shand  
Regulatory Affairs Associate  
2 Pearl Court  
Allendale, New Jersey 07401

MAR 18 2010

Re: K093670  
Trade/Device Name: Stryker Spine OASYS® System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNH, MNI, KWP  
Dated: February 16, 2010  
Received: February 18, 2010

Dear Ms. Pauline Shand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

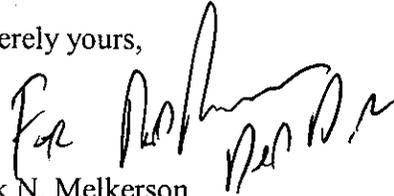
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K093670

Device Name: Line Extension to the Stryker Spine OASYS<sup>®</sup> System

Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput -T3), the Stryker Spine OASYS<sup>®</sup> System is intended for:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 -T3) spine.

The Stryker Spine OASYS<sup>®</sup> System can also be linked to the Xia<sup>®</sup> System, SR90D System and Xia<sup>®</sup> 4.5 Spinal System via the rod-to-rod connectors.

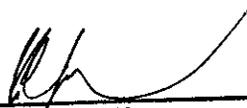
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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510(k) Number   K093670